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# Systematic Evidence Review

Number 27

# Screening for Visual Impairment in Children Younger than Age 5 Years: A Systematic Evidence Review for the U.S. Preventive Services Task Force

#### Prepared for:

Agency for Healthcare Research and Quality U.S. Department of Health and Human Services 540 Gaither Road Rockville, MD 20850 http://www.ahrq.gov

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#### Preface

The Agency for Healthcare Research and Quality (AHRQ) sponsors the development of Systematic Evidence Reviews (SERs) through its Evidence-based Practice Program. With guidance from the U.S. Preventive Services Task Force\* (USPSTF) and input from Federal partners and primary care specialty societies, the Evidence-based Practice Center at the Oregon Health Sciences University systematically review the evidence of the effectiveness of a wide range of clinical preventive services, including screening, counseling, and chemoprevention, in the primary care setting. The SERs—comprehensive reviews of the scientific evidence on the effectiveness of particular clinical preventive services—serve as the foundation for the recommendations of the USPSTF, which provide age- and risk-factor-specific recommendations for the delivery of these services in the primary care setting. Details of the process of identifying and evaluating relevant scientific evidence are described in the "Methods" section of each SER.

The SERs document the evidence regarding the benefits, limitations, and cost-effectiveness of a broad range of clinical preventive services and will help further awareness, delivery, and coverage of preventive care as an integral part of quality primary health care.

AHRQ also disseminates the SERs on the AHRQ Web site (<a href="http://www.ahrq.gov/clinic/uspstfix.htm">http://www.ahrq.gov/clinic/uspstfix.htm</a>) and disseminates summaries of the evidence (summaries of the SERs) and recommendations of the USPSTF in print and on the Web. These are available through the AHRQ Web site and through the National Guideline Clearinghouse (<a href="http://www.ngc.gov">http://www.ngc.gov</a>).

We welcome written comments on this SER. Comments may be sent to: Director, Center for Practice and Technology Assessment, Agency for Healthcare Research and Quality, 540 Gaither Road, Suite 3000, Rockville, MD 20850.

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<sup>\*</sup>The USPSTF is an independent panel of experts in primary care and prevention first convened by the U.S. Public Health Service in 1984. The USPSTF systematically reviews the evidence on the effectiveness of providing clinical preventive services--including screening, counseling, and chemoprevention--in the primary care setting. AHRQ convened the USPSTF in November 1998 to update existing Task Force recommendations and to address new topics.

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#### **Structured Abstract**

**Context:** Visual impairment is common in children younger than age 5 years. Early detection of visual impairment is thought to lead to better outcomes. New screening technologies, such as photorefractive screening, allow for the screening of very young children.

**Objective:** To review systematically the literature regarding the effectiveness of screening for visual impairment in children younger than age 3 years, and in children 3 years through 5 years of age.

**Data Sources:** We systematically searched MEDLINE® from 1966 through 1999 to identify studies regarding the prevalence of visual impairment, the effectiveness of treatment, the diagnostic accuracy of the screening tests, and the consequences of treated and untreated visual impairment. We also conducted hand-checks of bibliographies and extensive peer review to identify articles not captured through our main search strategy.

**Study Selection:** We included prevalence studies if they reflected the general population and evaluated subjects systematically for those conditions for which screening could be useful. We retained diagnostic accuracy studies if they evaluated commercially available tests and reported sensitivity and specificity results based on evaluation against a criterion standard. We included treatment outcome studies if they involved children younger than age 5 years and had a standard measure of visual acuity as an outcome measure. Studies of the consequences of treated or untreated visual impairment were used if the visual impairment was present by at least age 5 years.

A single reviewer examined titles and abstracts of articles and excluded those that clearly did not meet inclusion criteria. This reviewer then examined the full articles of the remaining studies to determine final eligibility.

**Data Extraction:** A single reviewer abstracted the relevant data from the included articles and entered them into a Microsoft Excel spreadsheet.

**Data Synthesis:** The prevalence of visual impairment in children 5 years of age and younger is between 7% and 8%. Three percent of children have amblyopia. Few data are available regarding the long-term consequences of untreated amblyopia.

We found no randomized trials of screening. Treating children younger than age years who have cataracts or strabismus may prevent the development of amblyopia. It is unclear whether treating young children with refractive errors associated with amblyopia would prevent the development of amblyopia. Furthermore, a theoretical risk exists that treating refractive errors in children younger than age 3 years may interfere with the normal development of the eye.

Indirect evidence supports the effectiveness of treatment for amblyopia and indicates treatment becomes more difficult with age. The cut-off age at which treatment is no longer effective depends on many factors, including the cause of the amblyopia. In general, treatment seems most effective when initiated before the grade-school years. Treatment for amblyopia may transiently decrease acuity in the nonamblyopic eye.

Treatment of refractive errors not associated with amblyopia is nearly always successful and does not depend upon the age of the child. As with the treatment of refractive errors associated with amblyopia, treating children younger than age 3 years in this circumstance may, at least theoretically, interfere with the normal development of the eye.

Few high-quality data are available regarding the performance of current screening tests.

None of these studies was performed in the primary care practice setting by usual caregivers.

Few data are available about the long-term consequences of visual impairment in children.

**Conclusions:** Visual impairment is common in childhood. Although early intervention is important for the prevention or treatment of visual impairment, treatment of certain refractive errors in children younger than age 3 years may interfere with the development of the eye. Few data are available regarding the performance of screening tests in the primary care practice setting.

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## I. Introduction

#### Vision Impairment and Screening

Visual impairment in young children is common, affecting 5% to 10% of all preschool children.<sup>1</sup> In 1996, the US Preventive Services Task Force (USPSTF) recommended screening all children for amblyopia and strabismus once before entering school, preferably between ages 3 and 4 years of age ("B Recommendation").<sup>1</sup> The USPSTF also recommended that clinicians be alert for signs of ocular misalignment when examining all infants and children. The Canadian Task Force on Preventive Health Care similarly found that fair evidence supports the inclusion of visual acuity tests in preschool-aged children.<sup>2</sup>

Based on these recommendations and the belief that early detection of visual impairment is important, many professional organizations have released practice guidelines, including the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), the American Academy of Ophthalmology (AAO), the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and the American Optometric Association (AOA).<sup>3</sup> Other advocacy groups, such as the nonprofit organization Prevent Blindness America,<sup>3</sup> have also developed guidelines. All these guidelines recommend screening children in the preschool years for both visual acuity and stereoacuity. These guidelines also suggest various specific tests for screening.

In 1998, the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration convened an expert panel to evaluate the evidence regarding the effectiveness of screening and to develop a set of harmonized guidelines based on the various available guidelines. MCHB has recently funded the AAP to continue the process of

developing uniform screening guidelines and to develop strategies to promote vision screening.

Although vision screening can occur in a variety of settings, such as schools, this review focuses on screening in the clinic setting.

One major problem with vision screening has been the challenge of evaluating young and sometimes uncooperative children. New screening technologies that allow for testing with only minimal involvement from the child have begun to become commonly available. These new tests may permit early diagnosis of conditions associated with amblyopia and therefore allow for primary prevention of amblyopia. By identifying children with impaired visual acuity, these devices may also enable clinicians to improve vision for this population during the preschool years. These devices were not evaluated when the USPSTF last reviewed this topic.

Despite significant interest in promulgating vision screening guidelines, questions have been raised about the efficacy of vision screening programs. In 1997, a systematic review sponsored by the British National Health Service (NHS) found a lack of high-quality research on the natural history of amblyopia and the efficacy of treatment.<sup>6</sup> This led the study's authors to question the value of preschool vision screening. This report met with significant criticisms,<sup>7</sup> including assertions that substantial animal data were ignored and that the report excluded retrospective clinical studies. Because clinicians may thus be confused about whether to screen young children routinely, we decided to re-examine vision screening in this age group.

To assist the USPSTF in updating its previous recommendations regarding vision screening in children through 5 years of age, the USPSTF staff at the Research Triangle Institute-University of North Carolina (RTI-UNC) Evidence-Based Practice Center (EPC) conducted a systematic review of high-quality scientific evidence regarding (1) the prevalence of visual disorders in children, (2) the effectiveness of available screening tests, (3) the effectiveness of

treatment, and (4) the impact of visual impairment on the individual. Because screening devices that can be used in very young children are now available, we evaluated vision screening separately for children less than 3 years of age and for children 3 through 5 years of age.

We did not address screening for color blindness or screening for disorders that indirectly cause visual impairment, such as retinoblastoma. This report does not address the screening of special populations, such as premature children or children with neuromuscular disorders, who have a high likelihood of having a visual impairment and would benefit from direct referral to an eye care specialist. Similarly, this report does not focus on children with profound visual impairment. This report focuses on amblyopia, conditions related to amblyopia, and refractive errors. Because terms related to these impairments can be complicated, we begin with a background summary of visual impairment and screening strategies.

#### **Amblyopia**

Types of Vision Impairment. – Amblyopia is reduced visual acuity in one or both eyes due to abnormal binocular interaction. Causes of amblyopia include ptosis, cataracts, strabismus, and unequal refractive errors between the 2 eyes (anisometropia). One large series found that strabismus accounted for 48% of the cases of amblyopia, refractive errors for 20% of the cases of amblyopia, and mixed strabismus and refractive errors for 32% of the cases. Cataracts and ptosis are rare in children. Primary prevention of amblyopia may be possible by early treatment of those conditions associated with amblyopia.

Amblyopia is associated with visual impairments that present early in life. If the visual impairments associated with amblyopia develop after 6 to 8 years of age of life, amblyopia usually does not arise. Amblyopia is considered to be a developmental disorder with an early

sensitive period.<sup>10,11</sup> This understanding has been one of the key points for the previous justification of preschool vision screening.

Treatment for amblyopia involves correcting the underlying cause of the amblyopia and reducing or eliminating the visual suppressive effect of the non-amblyopic eye. Typically this reduction or elimination is achieved by occluding the better eye with a patch. The duration of patching required depends on many factors, including the cause of the amblyopia, the density of the amblyopia, and the age of the child.

Refractive Errors Not Associated with Amblyopia. – The other common source of visual impairment is refractive error not associated with amblyopia. Examples include myopia (near-sightedness) and hyperopia (far-sightedness). These visual impairments may interfere with learning and other daily activities. Unlike amblyopia, these visual impairments remain correctable regardless of the age at which they are detected.

One challenge in evaluating refractive errors not associated with amblyopia is that refractive error often is associated with amblyopia. For example, hyperopia, the most common refractive error in children, can lead to the development of strabismus, which in turn can cause amyblopia.<sup>12</sup>

A second challenge in evaluating refractive errors in children is that the refractive state of the eye normally changes with the growth of the child. The eye grows rapidly between birth and 3 years of age, after which growth slows. To maintain vision during the time of rapid eye growth, the lens changes geometry. Animal models suggest that this process, known as emmetropization, does not occur normally if the eye does not receive visual stimulus. 13

**Vision Screening Strategies.** – Approaches to vision screening include assessing family history and eliciting concerns about the child's vision. Conditions associated with strabismus

can be found on physical examination. For example, cataracts can be found by examining the pupillary red light reflex. Clinicians can detect strabismus using the Hirschberg test, in which the corneal light reflexes are evaluated for symmetry. Another common way to assess for strabismus is the cover test, in which the child is asked to focus on an object. Each eye is covered while the other eye is observed for movement. A strabismic eye will move to focus on an object when the non-strabismic eye is covered.

Primary care providers can employ three approaches to screen formally for visual impairment. Traditional vision screening evaluates the ability of the child to recognize letters or symbols. Examples include the HOTV chart, in which the child identifies those letters, or the Lea symbols, in which the child identifies a circle, a square, a house, or an apple. These figures, or optotypes, can be presented in several ways, such as on hand-held cards or on wall charts. Furthermore, they have multiple layouts, such as spacing optotypes out in a uniform fashion or crowding optotypes together.

Traditional methods for vision screening can also be used to assess stereoacuity. In these tests, the child wears polarized glasses and looks at a picture. The child with normal stereoacuity will be able to see a figure. An example of this type of test includes the Random Dot E test, in which a child with normal stereoacuity will see a floating "E."

Binocular photoscreening is based on interpretation of a photograph of the pupils of the eyes. Patterns of reflections from the eyes can suggest refractive errors, strabismus, and cataracts. Two types of photoscreeners are presently available: those in which the screener interprets the photograph (such as MTI Photoscreener<sup>TM</sup>, Medical Technology and Innovations, Inc., Lancaster, Pa.; Visiscreen 100<sup>TM</sup>, Vision Research Corporation, Birmingham, Ala.) and

those in which a computer interprets the photograph (such as The EyeDx System<sup>TM</sup>, EyeDx, Inc., San Diego, Calif.).

The third available screening strategy involves automated devices that screen for refractive error (such as Retinomax<sup>TM</sup>, Nikon Inc., Japan; SureSight<sup>TM</sup>, Welch Allyn, Inc., Skaneateles Falls, NY). These devices directly refract each eye. This strategy evaluates one eye at a time and cannot, therefore, detect a misalignment between the eyes.

Unlike photoscreening, traditional vision screening tests directly for acuity and amblyopia. The newer technologies detect refractive errors and other conditions associated with amblyopia, but they do not directly evaluate acuity. They have the advantage of requiring only minimal cooperation from the child and can, therefore, be used to screen young children. However, some of the current devices, such as the MTI Photoscreener<sup>TM</sup>, require that the screener interpret a photograph of the eyes.

## II. Methods

#### Literature Search Strategy

To identify articles relevant to the questions of screening and treatment of visual impairment, we searched the MEDLINE database in numerous iterations from 1966 to the present. Two analytic frameworks (Figures 1 and 2) guided the literature searches. Analytic Framework A (Figure 1) depicts screening asymptomatic children for amblyopia or conditions associated with amblyopia. Analytic Framework B (Figure 2) depicts screening asymptomatic children for refractive error not associated with amblyopia. In each analytic framework, the overarching issue on which we sought evidence is the relationship between screening asymptomatic children for visual impairment and health outcomes.

Issues of screening and treatment are likely to be different for very young children and older children. For this reason, we paid special attention to differences between children less than 3 years of age and children between 3 and 5 years of age. Based on the analytic frameworks and the concern about differences in the age groups, we developed the following 8 key questions, also noted on the analytic frameworks:

- 1. What is the prevalence of visual impairment in children through 5 years of age?
- 2. Do reliable, accurate, and feasible screening tests exist that can be used to detect visual disorders in children less than 3 years of age or in children between the ages of 3 and 5 years? These visual disorders include amblyopia, strabismus, refractive errors associated with amblyopia, other more rare conditions associated with amblyopia such as cataracts or ptosis, and refractive error not associated with amblyopia.

- 3. Do detection and treatment of conditions associated with amblyopia before amblyopia has developed lead to better treatment outcomes (primary prevention)?
- 4. Under what conditions is the treatment of amblyopia successful?
- 5. Under what conditions is the treatment of refractive errors not associated with amblyopia successful?
- 6. Does improving vision result in improved health outcomes?
- 7. What are the adverse effects of screening?
- 8. What are the adverse effects of treatment?

We supplemented these MEDLINE searches by reviewing the bibliographies of included articles and other systematic reviews, meta-analyses, and evidence-based practice guidelines that addressed screening for visual impairment. Table 2 documents the results of the literature searches for each of the 8 key questions; Table 3 summarizes the outcomes of all items identified from review of abstracts to inclusion in evidence tables.

#### Literature Reviewed

One reader reviewed each title and abstract of the articles identified by the literature searches and excluded those that did not meet eligibility criteria. EPC staff then entered study design and outcomes data from the articles that had met inclusion criteria into seven evidence tables, organized by key question; we identified no literature about harms of screening. We assigned quality grades according to criteria established by the USPSTF Methods Work Group.<sup>17</sup>

## III. Results

## Key Question 1: Prevalence of Visual Impairment

Most data regarding the prevalence of visual impairment had been gathered as part of the assessment of screening tests, in which those who failed the screening examination were referred for further diagnostic evaluation. This strategy can underestimate the true prevalence because a person with a false-negative screening result will not be included. We were particularly interested in the prevalence in the general population and so excluded studies that could not be generalized to a defined population.

We found studies that evaluated elementary school-aged children <sup>18-21</sup> and adults<sup>22, 23</sup> (Evidence Table 1). We included studies of the prevalence of amblyopia in adults because untreated amblyopia is thought to persist through adulthood and amblyopia must first develop in childhood.

The overall prevalence of visual impairment, including all refractive errors, is 7% to 8.2%. The prevalence of amblyopia is 2.9% to 3.9%.

#### **Key Question 2: Accuracy of Screening Tests**

We established inclusion and exclusion criteria to select only high-quality studies of vision screening tests for children less than 5 years of age. We used 4 criteria: (1) all or a random sample of those who passed and all those who failed the screening test must receive a formally described "gold standard" eye examination; (2) the person performing the examination must be masked to the outcome of screening; (3) the criteria for failing the screening examination must be described; and (4) the test must be commercially available. Because the goal of screening is to detect children who have visual impairment, we considered only evidence that reported results in which individual children was the unit of analysis, not individual eyes.

One systematic review,<sup>24</sup> which used these criteria to assess vision screening tests for children ages 2 to 5 years of age, identified 4 articles.<sup>25-28</sup> However, we excluded 1 of these articles from our review because the study may not have been adequately masked.<sup>28</sup> Our search identified 3 additional studies that evaluated children less than 3 years of age (Evidence Table 2)<sup>29-31</sup> and 1 additional study that evaluated children over 3 years of age.<sup>32</sup>

None of the articles that met our inclusion criteria evaluated the role of screening for family history or parental concern. Similarly, none of the articles evaluated the accuracy of the physical examination to detect visual impairment such as cataracts or strabismus. None of the studies was performed in the primary care practice settings using usual screening procedures.

Accuracy of Screening Tests in Children Younger than Age 3 Years. We found 3 studies of the MTI photoscreener<sup>TM</sup> that evaluated young children (Table 4). The first included 103 children younger than 3 years of age.<sup>29</sup> Of these, 74% had visual impairment. Eighteen volunteers, none of whom had previous experience with photoscreening, evaluated the photographs. From these readers, the sensitivity ranged from 37% to 88% and the specificity

ranged from 40% to 88%. No single reader achieved sensitivity and specificity greater than 70%. The average condition specific sensitivities were 6% for cataract, 65% for refractive error, and 39% for strabismus.

The second study of the MTI photoscreener™ evaluated 105 children between 12 and 44 months old (no average age given) in an ophthalmology clinic.<sup>31</sup> Two readers interpreted the photographs. In a population with 60% prevalence of visual impairment, the sensitivity and specificity was 56% and 79% by one reader and 61% and 86% by the other reader.

The third study of the MTI<sup>TM</sup> photoscreener evaluated 392 children, with an overall average age of 22 months (80% less than 36 months, 20% between 36 and 47 months old).<sup>30</sup> Of these children, 74%had a visual impairment. Each photograph was evaluated by 1 of 2 readers familiar with photoscreening. The overall sensitivity was 65% and the specificity was 87%. Condition-specific sensitivities include 20% for cataract, 33% for refractive error, and 55% for strabismus.

One study evaluated the performance of the Visiscreen 100 in 113 children between 6 months and 6 years of age. No average age was provided. The prevalence of visual impairment in the study population was 12%. Overall sensitivity and specificity were 85% and 94%. No condition-specific sensitivities were provided.

Accuracy of Screening Tests in Children Aged 3 to 5 Years. One study of photoscreening and two studies of traditional vision screening that met the inclusion criteria addressed screening children 3 years of age and older (Table 5). The study of photoscreening evaluated 57 patients in an ophthalmology clinic with the Visiscreen 100 as interpreted by experts in photoscreening.<sup>27</sup> The age ranged from 3 months to 8 years of age. The data presented suggest that the average age was greater than 4 years of age. Of these subjects, 12%

had a visual disorder. Overall, the sensitivity was 91%; specificity, was 74%. Condition-specific sensitivities include 100% for cataracts and 93% for strabismus.

The first study of traditional vision screening evaluated 1,245 kindergarteners with the Snellen E test and the Titmus Stereotest. Children who were unable to perform the Snellen E test were evaluated with Stycar Graded balls. All children who failed these tests or failed an experimental photoscreener that was also being evaluated were referred for diagnostic evaluation. An additional 20% of the kindergarteners were also referred. Within this subpopulation, the overall sensitivity was 33% and the specificity was 97%. When these numbers are applied to the original population, the estimated sensitivity is 9% to 12.5% and the specificity is 99%. Within the subpopulation, condition-specific sensitivities include 33% for refractive error, 33% for strabismus, and 50% for combined refractive error and strabismus.

The other study of traditional vision screening evaluated a total of 3,434 kindergarteners over 3 years of age. Public health nurses administered the screening. In the first year, the children were screened by the Cambridge Crowding Cards, which include the letters "A," "H," "O," "T," "U," "V," and "X" (Haag Streit UK, London, England), and the Hirschberg test.

During the second year, a test of stereoacuity, the Stereofly (Titmus Optical Co., Petersburg, Va.) was added. During the third year, the Hirschberg test was dropped. All children who failed were referred. For each child who was referred, another child, usually the next in line, was referred. The overall sensitivity, scaled to the total population, ranged from 60% to 71%, and the specificity ranged from 70% to 80%. During the second year of the study, when both the Hirschberg test and the stereoacuity test were used, the overall sensitivity was the highest (84%) and the specificity the lowest (65%). The sensitivity and specificity were similar in the first year when the stereoacuity test was not used (sensitivity 62%, specificity 76%) to the third year, when

the Hirschberg test was not used (sensitivity 60%, specificity 80%). Among those in the referred group, the condition-specific sensitivities were 78% to 100% for strabismus and 92% to 100% for amblyopia.

#### Key Questions 3 and 4: Effectiveness of Treatment

**Primary Prevention of Amblyopia.** — Early treatment of those conditions associated with amblyopia may prevent the development of amblyopia. However, few data are available regarding the effectiveness of primary prevention.

Strabismus. One study evaluated surgical treatment for strabismus in infants. Among 129 children treated by 2 years of age, 36.4% had normal stereopsis by 5 to 9 years of age.<sup>33</sup> The most important factor in the outcome of treatment was the duration of the strabismus before surgical correction.

Refractive error. One study evaluated whether early treatment of hyperopia would prevent the development of strabismus.<sup>34</sup> A community wide screening program identified 371 6-month-old children with hyperopia. These children were randomly allocated to spectacle treatment or no treatment. At 3.5 years, early treatment did not affect the development of strabismus (26% in untreated group, 31% in treated group). Although the study suggests that the final visual acuity in the worse eye was significantly better in those who were compliant with therapy (97% at least 20/30 in the treated versus 87% in the untreated group) no information is provided about whether this final acuity measure was corrected or uncorrected.

Cataracts. One study of cataracts included 25 subjects who had been treated for a cataract before 1 year of age.<sup>35</sup> Of these children, 20% had achieved at least 20/40 vision by 5 years of age, but only those children who had had undergone surgery by 17 weeks of age experienced improvement in visual acuity.

Treatment of Amblyopia. — We found no trials comparing treatment to no treatment for amblyopia. Although such a study has been called for based on the British NHS report, many consider such a trial to be unethical. Indirect evidence of the effectiveness of treatment comes from cross-sectional studies comparing the prevalence of visual impairment in those who have been screened compared to those who have not been screened and from cohort studies of those who have been diagnosed with visual impairment.

Natural history of untreated amblyopia. One year after evaluating the prevalence of visual impairment among four- to six-year-olds residing in inner-city Baltimore, <sup>19</sup> a follow-up study found that only 30% of children had received evaluation or completed treatment by an eye care specialist. <sup>20</sup> Changes in the children with amblyopia who did not receive appropriate treatment over that year provide information about the natural history of untreated amblyopia. Overall, 15 children were found to be amblyopic at both screenings and failed to comply with therapy. <sup>34</sup> Of these children, one (who wore glasses sporadically) had slight improvement in the amblyopic eye; four had deterioration in vision. These data suggest that amblyopia is unlikely to improve without therapy.

Prevalence rates of amblyopia in screened and unscreened populations. Sweden has an aggressive vision screening program, with repeat screening beginning with objective measures in infancy and extending to formal measures through 10 years of age. A retrospective cohort study found that by 10 years of age, the prevalence of amblyopia is 0.03%.<sup>21</sup> This rate, which is much lower than the 3% rate found in the other prevalence studies, suggests that screening may reduce amblyopia. Similarly, a study in Israel found that the prevalence of amblyopia in 8-year-old children who received screening, including retinsoscopy, between 1 and 2.5 years of age was 1%, compared to 2.6% in an unscreened population.<sup>37</sup>

Outcomes of those Treated for Amblyopia. Evidence of the effectiveness of treatment for children with amblyopia comes from retrospective and prospective cohort studies. We considered improvement to be achievement of at least 20/40 in the amblyopic eye or clear evidence in another measurement that the eye had improved. Of the prospective studies in this review, between 41% and 96% of persons with amblyopia had improved visual acuity after treatment. These studies had between 25 and 255 subjects (mean, 112). Of the retrospective studies, between 40% and 95% of those with amblyopia achieved better visual acuity. These studies had between 51 and 961 subjects (mean, 280).

These cohort studies are not directly comparable. The types of visual impairment treated, the treatment type, treatment duration, individual compliance with therapy, and length of follow-up all varied among the studies; this heterogeneity precluded meta-analysis. In general, however, treatment does seem to be at least partially successful.

Two studies of treatment for amblyopia found that successful outcome depended on earlier treatment. The larger of these studies, a retrospective analysis of 407 children with strabismic amblyopia, demonstrated that treatment efficacy is highest for children younger than 3 years of age. Furthermore, treatment efficacy steadily decreased after 3 years of age; by 12 years of age, treatment was ineffective.

The stability of the improvement for those treated with amblyopia is unclear. None of the studies included in this review followed patients into adulthood.

Treatment of Refractive Errors Not Associated with Amblyopia. — Treatment of refractive errors not associated with amblyopia is by spectacle correction. In 1 retrospective cohort study, 98% of preschool children corrected to normal vision. 45

#### **Key Question 5: Clinical Consequences**

Few data are available regarding the consequences of visual impairment that is untreated before 5 years of age. The literature searches yielded 1 study on the association between visual impairment and learning or intelligence. In this study of 10-year-old children from England, subjects with amblyopia had a statistically significant lower score on the British Ability Scales than children with normal vision (98.4 versus 100; standard deviation 15). The importance of this finding is unclear, because the absolute difference was small. Furthermore, a cross-sectional study cannot establish causality. However, a small shift in ability to learn or intelligence may have an important impact on society.

We were interested in the relationship between amblyopia and quality of life. Because amblyopia untreated in the early years may be permanent, we searched for data regarding the effect of amblyopia on persons of all ages.

One study explored the relationship between amblyopia and quality of life.<sup>52</sup> This survey was administered to 45 adults with amblyopia but without strabismus. Of the respondents, nearly 50% reported that amblyopia interfered with schooling and work and nearly 75% reported that amblyopia affected their self-image. These subjects were recruited in an academic ophthalmologic practice, raising questions about generalizability. Furthermore, this study had a response rate of 56%, which raises concern about selection bias.

Amblyopia may be a risk factor for future total blindness. A retrospective study from Finland found 23 cases in which people with amblyopia subsequently become totally blind. The authors reviewed the prevalence of amblyopia and the population from which these cases arose to determine the risk of loss of vision in the non-amblyopic eye. The risk of vision loss  $(1.75 \pm 0.30)$  cases per 1,000 persons among those with amblyopia was found to be greater than

among the general population (0.66 cases per 1,000 persons). Accidental trauma was associated with more than half of the cases of total vision loss in those with amblyopia. This study may be biased by the assumptions regarding prevalence and population size.

Although certain jobs require normal stereoacuity (depth perception), such as piloting aircraft, we were unable to find any study detailing the relationship between amblyopia and job performance. However, the requirement for the absence of amblyopia for a given occupation does not mean that there is a basis for such a requirement. The ability to perform jobs that require near-work, however, is more likely to be affected by amblyopia.

Little is known about the consequences of untreated visual impairments in young children. Furthermore, few data are available regarding the long-term burden of suffering caused by amblyopia.

#### Key Questions 6, 7, and 8: Harms of Screening and Treatment

No article that met the criteria for inclusion in this review detailed any harm directly resulting from screening or mentioned any harm from an eye examination, such as a side effect from dilating the eyes. No data were found regarding the harms of false-positive screening.

One study of the treatment of amblyopia found that visual acuity of the non-amblyopic eye can decrease on average to 20/182 as a result of patching.<sup>48</sup> However, this loss of visual acuity was not permanent and resolved weeks after therapy was ended.

A potential harm of early treatment visual impairment is interference with the normal development of the eye. Because the development of the eye, or emmetropization, partially depends upon the quality of image that an eye receives, some experts have suggested that interfering with this image, even by correction, may impair normal development.<sup>8</sup> An analysis of the study of early treatment of hyperopia found that emmetropization did not occur in 42% of

treated children compared to 31% of those not given spectacles.<sup>54</sup> Although the precise course of normal emmetropization is unclear, these data suggest that early intervention may be harmful.

#### IV. Discussion

Visual impairment is common, affecting 5% to 10% of children under 5 years of age. No prospective randomized trial has evaluated the impact of vision screening among children. This review suggests that there are a different set of screening considerations for children less than 3 years and those who are 3-years to 5 years.

#### Children Younger Than Age 3 Years

Early detection of cataracts and strabismus leads to improved outcome. Few data support early treatment of refractive errors. Although uncontrolled studies suggest that early initiation of treatment for amblyopia results in improved outcomes, there is at least a theoretical concern that early correction of refractive error can interfere with the normal development of the eye.

Components of the physical examination, such as red reflex examination, the cover test, or the Hirschberg test, can screen for cataracts and strabismus. We were unable to find any studies of the accuracy of the physical examination for the detection of visual impairment.

Newer screening technology can detect cataracts, strabismus, and refractive error. The reports of the accuracy of the new screening tests are promising, but no evaluation has been done in the primary care practice setting with the tests administered as would be done by those usually responsible for screening. Additionally, little is known about how these new tests compare to the physical examination itself.

## Children Aged 3 to 5 Years

Detection of amblyopia or those conditions associated with amblyopia is important during the preschool years because treatment for amblyopia is more difficult and eventually ineffective with increasing age. A potential harm of the treatment of amblyopia is a transient decrease in visual acuity in the non-amblyopic eye.

Treatment of refractive error is usually successful. Furthermore, treatment of refractive errors is unlikely to interfere with the development of the eye after 3 years of age.

Although the new automated screening devices can potentially make screening easier, it should be recognized that these tests screen for visual acuity and amblyopia indirectly, by detecting associated conditions such as refractive errors and strabismus. Little is known about the performance of these new tests or of traditional vision screening in the primary care practice setting.

## **Limitations of this Analysis**

This review has several limitations related to the types of evidence that we included.

First, we did not consider animal data. The previous Task Force found that animal models provide fair evidence that early intervention improves the prognosis for children with amblyopia and strabismus.<sup>1</sup>

Second, studies that we excluded did not meet high standards. Although this strategy minimizes potential bias, we may still have excluded important studies. For example, this review did not consider studies that lacked a clearly defined gold standard eye examination.

Both the previous Task Force and the Canadian Task Force on Preventive Health Services considered a study that evaluated the impact of preschool vision screening on the prevalence of visual disorders 6 to 12 months later. This study compared the prevalence in 2 cohorts of

children; one received preschool vision screening, and the other did not. Of the children in the screened cohort, 10% had a visual impairment as did 15% in the unscreened cohort. However, the diagnosis of visual impairment was based on a screening test, the Illiterate E chart, not a complete eye examination. This may also account for the high prevalence found in this study.

Our review also did not consider studies of screening tests that reported only positive or negative predictive value. Examples of these include a report that photoscreening has a positive predictive value of 84% for the diagnosis of strabismus and a study of traditional vision screening that found a negative predictive value of 98%. We omitted these studies because we believed that understanding the *tradeoffs* between sensitivity and specificity was important. Similarly, we did not consider studies that evaluated the feasibility and reliability of these screening tests. Although these are important factors when choosing a screening strategy, in our view establishing test accuracy is the first important step.

#### Recommendations for Future Research

A randomized trial of preschool vision screening is unlikely ever to be conducted. Other study designs, however, can improve the available evidence regarding the effectiveness of screening and demonstrate the features of a successful screening strategy. Visual impairment is an active field of research, and some of these studies are under way. This section reviews some studies currently in progress and suggests studies that, if performed, could help clarify some of these important issues.

The Amblyopia Treatment Study, funded by the National Institutes of Health, is a prospective randomized trial to compare the relative effectiveness of occlusion and penalization in the treatment of amblyopia. This study may provide a standard of treatment for preschoolaged children with amblyopia.

Interest is growing in the impact of vision screening on children younger than preschool age. A study in England is evaluating the impact of frequent eye examinations by an orthoptist before 3 years of age.<sup>60</sup> Outcome will be assessed by a "gold standard" ophthalmologic examination at 37 months.

Few data are available regarding the performance of vision screening tests in the primary care setting. The Eye Screening Project, now in development, will compare various commercially available screening tests in children ages 12 to 18 months and 36 to 60 months (Alex Kemper, MD, MPH, MS, personal communication, December 2000). Evaluation will occur in a pediatric office-based network. Selected children will receive a standardized diagnostic evaluation by an eye care specialist.

Photoscreening is an emerging technology. New devices are likely to be developed. As they are tested, we will gain a better understanding of the role of the currently available and newer devices.

The Vision in Preschoolers (VIP) Study Group has received pilot funding from the National Eye Institute to develop a protocol to assess preschool vision screening guidelines.<sup>61</sup>

This group will also develop a protocol to evaluate the performance of lay screeners teamed with health professionals to screen preschoolers at high risk for visual impairment.

A population-based case-control study could evaluate the effectiveness of current screening programs. If screening and treatment reduce future visual impairment incidence or severity, fewer of the cases with visual impairment should have been screened and treated than controls without visual impairment. A similar strategy can be used to assess the impact of visual impairment on learning and education.

Little is known about the harms of false-positive screening, wearing glasses, or having an eye patched. Focus groups and surveys could be carried out to identify such adverse effects and understand their duration and severity.

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Figure 1. Vision Impairment Screening: Analytic Framework A

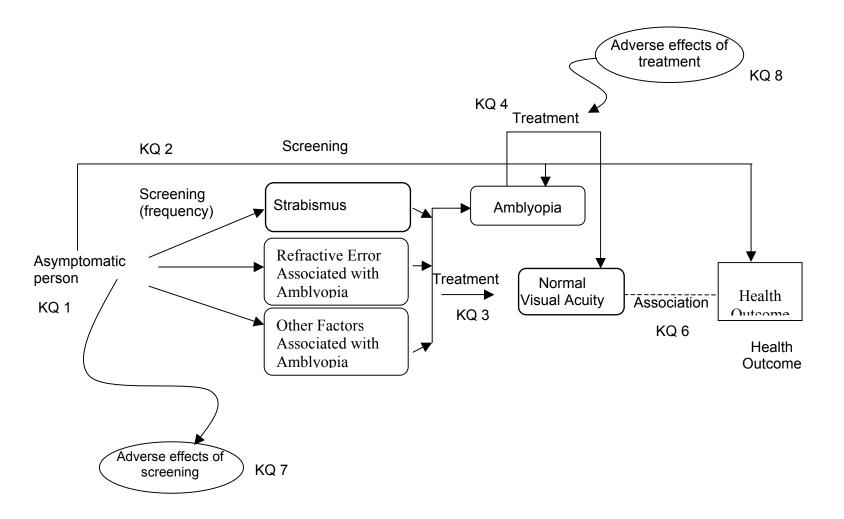


Figure 2. Vision Impairment Screening: Analytic Framework B

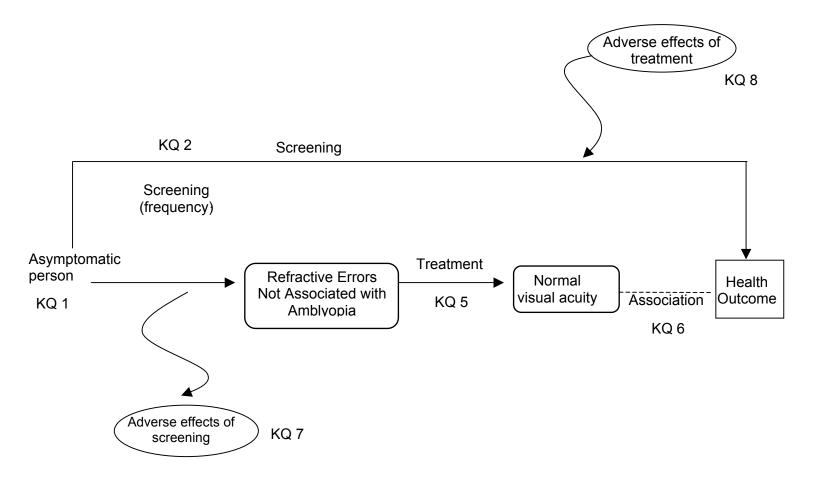


Table 1. Vision Impairment: General Inclusion and Exclusion Criteria

Category	Inclusion	Exclusion
Databases	MEDLINE	Other databases
Languages	English only	Other languages
Populations	Humans only	Animal studies
Study design	All	No editorials, letters to editors

**Table 2. Vision Impairment: Search Strategy Results** 

Search	Strategy for Key Question 1	
1	Explode vision disorders	30,455
2	Explode prevalence	41,870
3	2 and 3	413
4	Limit 4 to (human and English language and (newborn infant < birth to 1 month > or infant < 1 to 23 months > or preschool child < 2 to 5 years >))	128
Search	Strategy for Key Question 2	
1	Explode vision tests	14,570
2	Limit 1 to (human and English language and (newborn infant < birth to 1 month > or infant < 1 to 23 months > or preschool child < 2 to 5 years >))	1439
3	Explode randomized controlled trials, or explode single-blind method, or explode double-blind method, or explode random allocation	105,639
4	2 and 3	48
Search	Strategy for Key Questions 3 and 4	
1	Explode amblyopia	3,252
2	Treatment outcome	81,783
3	1 and 2	69
4	Limit 3 to (human and English language)	56
Search	Strategy for Key Question 5	
1	Explode vision disorders	30,455
2	Explode amblyopia	3252
3	1 not 2	27,203
4	Explode treatment outcome	86819

5	3 and 4	268
6	Limit 5 to (human and English language and (newborn infant < birth to 1 month > or infant < 1 to 23 months > or preschool child < 2 to 5 years >))	36
8	Explode refractive errors	11,755
9	4 and 8	660
10	Limit 9 to (human and English language and (newborn infant < birth to 1 month > or infant < 1 to 23 months > or preschool child < 2 to 5 years >))	38
11	10 not 6	36
Search St	rategies for Key Question 6	
1	Explode amblyopia	3,252
2	Blindness	9,578
3	1 and 2	73
4	Limit 3 to (human and English language)	33
1	Explode risk, or explode risk factors, or explode risk-taking	219,156
2	Explode amblyopia, or explode vision, monocular, or "monocular blindness"	4,335
3	1 and 2	54
3 4	1 and 2 Not in the "Wound and injury" section	54 52
4 5	Not in the "Wound and injury" section	52
4 5 Table 2	Not in the "Wound and injury" section Limit 4 to (human and English language)	52
4 5 Table 2 Search St	Not in the "Wound and injury" section Limit 4 to (human and English language)  . Vision Impairment: Search Strategy Results (continued)  rategies for Key Question 6 (continued)	52 39
4 5 Table 2 Search St	Not in the "Wound and injury" section Limit 4 to (human and English language)  Vision Impairment: Search Strategy Results (continued)  rategies for Key Question 6 (continued)  Explode amblyopia, or explode vision disorders	52 39 30,455
4 5 Table 2 Search St	Not in the "Wound and injury" section Limit 4 to (human and English language)  Vision Impairment: Search Strategy Results (continued)  rategies for Key Question 6 (continued)  Explode amblyopia, or explode vision disorders Explode learning	52 39
4 5 Table 2 Search St	Not in the "Wound and injury" section Limit 4 to (human and English language)  Vision Impairment: Search Strategy Results (continued)  rategies for Key Question 6 (continued)  Explode amblyopia, or explode vision disorders	30,455 116,708
4 5 Table 2 Search St 1 2 3	Not in the "Wound and injury" section Limit 4 to (human and English language)  Vision Impairment: Search Strategy Results (continued)  rategies for Key Question 6 (continued)  Explode amblyopia, or explode vision disorders Explode learning Explode education	30,455 116,708 269,574
4 5 Table 2 Search St 1 2 3 4	Not in the "Wound and injury" section Limit 4 to (human and English language)  Vision Impairment: Search Strategy Results (continued)  rategies for Key Question 6 (continued)  Explode amblyopia, or explode vision disorders Explode learning Explode education 2 or 3	30,455 116,708 269,574 378,968
4 5 Table 2 Search St 1 2 3 4 5	Not in the "Wound and injury" section Limit 4 to (human and English language)  Vision Impairment: Search Strategy Results (continued)  rategies for Key Question 6 (continued)  Explode amblyopia, or explode vision disorders Explode learning Explode education 2 or 3 1 and 4	30,455 116,708 269,574 378,968 1,418
4 5 Table 2 Search St 1 2 3 4 5 6	Not in the "Wound and injury" section Limit 4 to (human and English language)  Vision Impairment: Search Strategy Results (continued)  rategies for Key Question 6 (continued)  Explode amblyopia, or explode vision disorders Explode learning Explode education 2 or 3 1 and 4 Limit 6 to (human and English language and age 0-5 years)	30,455 116,708 269,574 378,968 1,418 211
4 5 Table 2 Search St 1 2 3 4 5 6	Not in the "Wound and injury" section Limit 4 to (human and English language)  Vision Impairment: Search Strategy Results (continued)  rategies for Key Question 6 (continued)  Explode amblyopia, or explode vision disorders Explode learning Explode education 2 or 3 1 and 4 Limit 6 to (human and English language and age 0-5 years)  Explode amblyopia	30,455 116,708 269,574 378,968 1,418 211
4 5 Table 2 Search St 1 2 3 4 5 6	Not in the "Wound and injury" section Limit 4 to (human and English language)  Vision Impairment: Search Strategy Results (continued)  rategies for Key Question 6 (continued)  Explode amblyopia, or explode vision disorders Explode learning Explode education 2 or 3 1 and 4 Limit 6 to (human and English language and age 0-5 years)	30,455 116,708 269,574 378,968 1,418 211
4 5 Table 2 Search St 1 2 3 4 5 6	Not in the "Wound and injury" section Limit 4 to (human and English language)  Vision Impairment: Search Strategy Results (continued)  rategies for Key Question 6 (continued)  Explode amblyopia, or explode vision disorders Explode learning Explode education 2 or 3 1 and 4 Limit 6 to (human and English language and age 0-5 years)  Explode amblyopia Explode vision, monocular, or "monocular blindness"	30,455 116,708 269,574 378,968 1,418 211 3,252 1,127
4 5 Table 2 Search St 1 2 3 4 5 6	Not in the "Wound and injury" section Limit 4 to (human and English language)  Vision Impairment: Search Strategy Results (continued)  Explode amblyopia, or explode vision disorders Explode learning Explode education 2 or 3 1 and 4 Limit 6 to (human and English language and age 0-5 years)  Explode amblyopia Explode vision, monocular, or "monocular blindness" 1 or 2	30,455 116,708 269,574 378,968 1,418 211 3,252 1,127 4,335

6	Limit 5 to (human and English language)			
Search	Strategy for Key Question 7			
1	Explode amblyopia	3,252		
2	Explode mass screening/ae [Adverse Effects]	144		
3	1 and 2	0		
4	Explode vision disorders or "vision impairment"	30,508		
5	2 and 4	0		
6	Explode vision	83,307		
7	2 and 6	0		
		_		
Search	Strategy for Key Question 8			
1	Explode anxiety	22,603		
2	Explode emotions, or explode shame, or "embarrassment"	65,764		
3	1 or 2	65,764		
4	Explode amblyopia	3,252		
5	3 and 4	5		
6	Explode eyeglasses	3,539		
7	2 and 6	85		
8	5 or 7	87		
9	Limit 8 to (Human and English Language)	59		

Table 3. Summary Results from Literature Searches and Reviews

Search and Review Results	KQ1	KQ2	KQ3 and KQ4	KQ5	KQ6	KQ7	KQ8
Number of Abstracts							
From literature search	128	48	56	36	355	0	59
From supplemental search	6	15	16	1	1	0	1
Reviewed	134	63	75	37	356	0	60
Excluded at abstract review phase Included for full article review	118 16	39 24	31 44	27 10	345 11	0	55 5
Number of Articles	. •			. •	• •	J	Ū
Excluded after full review Included in Evidence	10	17	25	9	8	0	3
Summary	6	7	6,13	1	3	0	2
Included in Evidence Tables	6	7	3,13	1	3	0	2

Table 4. Accuracy of Screening Tests in Children Younger than Age 3 Years

Test	Study	Sensitivity*	Specificity*	Prevalence
MTI Photoscreener	Tong et al., 1998 <sup>29</sup>	37% – 88%	40% – 88%	74%
	Cooper et al., 1999 31	56%	79%	60%
	Cooper et al., 1999 31	79%	86%	60%
	Tong et al., 2000 <sup>30</sup>	65%	87%	74%
Visiscreen 100	Cogen and Ottemiller, 1992	65%	87%	12%

<sup>\*</sup>No single screener achieved both sensitivity and specificity of greater than 70%.

**Table 5. Accuracy of Screening Tests in Children Aged 3 to 5 Years** 

Test	Study	Sensitivity	Specificity	Prevalence
Visiscreen 100	Morgan and Johnson, 1987	91%	74%	12%
Snellen E and Titmus stereotest or Stycar Graded balls	Kennedy et al., 1995 <sup>25</sup>	33%	97%	9% – 12.5%
Cambridge Crowding Cards and Hirschberg test	Robinson et al., 1999 <sup>32</sup>	62%	76%	Not reported
Cambridge Crowding Cards and Stereofly	Robinson et al., 1999 <sup>32</sup>	60%	80%	Not reported
Cambridge Crowding Cards, Hirschberg test, and Stereofly	Robinson et al., 1999 <sup>32</sup>	84%	65%	Not reported

**Evidence Table 1. Key Question 1: Prevalence of Visual Impairment** 

Source: Author, Year	Research Design	Subjects	Measurements	Results	Quality*
Kohler & Stigmar, 1978 <sup>18</sup>	Cross- sectional	2,173 seven year old children in Sweden were screened, those with worse than 20/20 vision were referred to an ophthalmologist	Complete eye exam	310 children were referred (14.2% of total population); 5.8% of these children had amblyopia (0.8% of total population); 6.1% of referred group needed glasses; of the 40 with significant visual impairment, 29/40 did not have previous vision screening and 11/40 screened normal at 4 years of age; the risk of finding a new significant eye disorder in a school entrant was more than 6 times greater for a child who was not examined in his preschool years, and the risk of finding an amblyopic child was more than 10 times greater	N/A
Vinding et al., 1991 <sup>22</sup>	Cross- sectional	1000 adults in Denmark between 60- 80 years old	Complete eye exam	2.9% of the population had amblyopia	N/A
Preslan & Novak, 1996 <sup>19</sup>	Cross- sectional	680 children were recruited from an inner city school system; 75% of these children were between preschool and second grade	Complete eye exam	173/680 (25.4%) of these children failed initial vision screening. 76 of those who failed did not pass a second screening; 3.9% of the children that failed two screening exams had amblyopia; the etiology for the amblyopia included strabismus (44%), spherical anisometropis (26%), astigmatic anisometropia (18%), and bilateral ametropia (12%); overall, 8.3% were found to have refractive errors requiring correction	N/A
Jakobsson et al., 1997 <sup>21</sup>	Retrospective cohort	All children (3,126) born in 1982 in 3 swedish communities	Visual acuity screening at age 4 to 5.5 years of age, 7 years of age, and 10 years of age	Prevalence of amblyopia at 10 yrs was 0.03%	Good
Attebo et al., 1998 <sup>23</sup>	Cross- sectional	In Australia, 3654 persons>49 years	Complete eye exam	3.2% of the population was found to have amblyopia; of the 118 with amblyopia, 9 were unaware that they had a visual impairment	N/A
Preslan & Novak, 1998 <sup>20</sup>	Cross- sectional	2,285 preschool children in inner city schools	Complete eye exam  - Not applicable.	5.3% of the children had amblyopia and 12.5% of the children had refractive errors, the cause of the amblyopia was equally divided between strabismus, anisometropia, and astigmatism	N/A

**Evidence Table 2. Key Question 2: Screening Test Performance** 

Source:	Research				
Author, Year Tong et al.,	Design Cross-	Subjects 103 children between	Measurements Complete eye	Results The prevalence of visual	Quality Poor
1998 <sup>29</sup>	sectional	1 and 44 months of age seen in an ophthalmology clinic and screened with the MTI Photoscreener™	exam	disorder was 74%; depending on the reader of the photograph, the sensitivity ranged from 37% to 88%; the range of specificity was 40% to 88%; no single reader had both sensitivity and specificity >70%	
Tong et al., 2000 <sup>30</sup>	Cross- sectional	392 children younger than 3 years old in an ophthalmology clinic screened with the MTI Photoscreener™	Complete eye exam	The prevalence of visual impairment was 43%; the range of test sensitivity was 56 to 65%; specificity 87 to 91%	Poor
Cooper et al., 1999 <sup>31</sup>	Cross- sectional	105 children between 12 and 44 months old seen in an ophthalmology clinic screened with the MTI Photoscreener™	Complete eye exam	The prevalence of visual impairment was 60%. One photograph reader had a sensitivity of 56% and specificity of 79%. Another reader had a sensitivity of 61% and specificity of 86%	Poor
Kemper et al., 1999 <sup>24</sup>	Systematic review (Includes <sup>22, 23,24</sup> )	3 studies that met inclusion criteria for the USPSTF review	Complete eye exam	Titmus stereotest and either Snellen E or stycar graded balls: pop. prevalence= 6%, sensitivity between 9% and 12.5%, specificity= 99%; Visiscreen 100TM: pop prevalence= 60%, sensitivity= 85%, specificity= 94%; Visiscreen 100TM: pop. prevalence= 12%, sensitivity= 91%, specificity= 74%.	Good Systematic Review
Robinson et al., 1999 <sup>32</sup>	Cross- sectional	3,434 kindergartenters screened with either Cambridge Crowding cards and Hirschberg test, or cards, Hirschberg and Stereofly, or cards and stereofly	Complete eye exam on all who failed and sample of passes	sensitivity ranged from 60 to 84% and specificity 65-80%. See article for detailed sens and spec data	Fair

**Evidence Table 3. Key Question 3: Early Detection of Amblyogenic Factor** 

Source: Author,	Research	·			
Year	Design	Subjects	Measurements	Results	Quality
Cheng et al., 1991 <sup>35</sup>	Retrospective cohort	25 infants with unilateral cataracts, 7 of whom also had strabismus, corrected before 1 year of age and then treatment for amblyopia	Visual acuity five years later	s 20% had visual acuity of least 20/40; the best results were achieved for those treated before 17 weeks of age	Fair
Birch et al., 2000 <sup>33</sup>	Prospective cohort	129 children with esotropia treated by 5 to 24 months of age with surgery	Stereopsis at 5 to 9 years of age	36.4% had stereopsis	Fair
Ingram et al., 1990 <sup>34</sup>	RCT	371 6 months old with hyperopia	Dilated eye exam (unmasked) up to every 3 months and at age 3.5 years	24% in both groups developed strabismus	Poor

**Evidence Table 4. Key Question 4: Treatment of Amblyopia** 

Source:	Research				
Author, Year	Design	Subjects	Measurements	Results	Quality
Bradford et al., 1992 <sup>50</sup>	Retrospective cohort	15 patients treated at University of lowa between 1970 and 1989 for media opacity and amblyopia, average age unclear, treated with occlusion therapy		87% of subjects achieved 20/40 or better	Poor
Hiscox et al.,	Retrospective	368 patients with an	Visual acuity	40% achieved at least	Fair
1992 <sup>43</sup>	cohort	average age of 4 years 7 months with amblyopia identified by a screening program in England		20/30 vision; improvement was similar across all age groups	
Rutstein & Fuhr 1992 <sup>47</sup>	, Retrospective cohort	64 subjects, with an average age of 9 years, with amblyopia from anisometropia or strabismus treated with occlusion	Improvement in visual acuity	Of the subjects treated by 7 years of age, 90% showed some acuity gain; of those treated after 8 years of age, 77% showed some gain in visual acuity; at least 67% of those with amblyopia (18 subjects total) followed for 1 year lost some of the acuity gain after cessation of therapy	Fair
Epelbaum et al. 1993 <sup>48</sup>	, Retrospective cohort	407 children with strabismic amblyopia in France who were treated by, on average, 57 months of age		Of those subjects who began treatment by 21 months of age, 70% showed improvement; if treatment is begun between 28 and 33 months of age, 95% improve; around 144 months of age, treatment does not lead to improvement	Fair

**Evidence Table 4. Key Question 4: Treatment of Amblyopia** 

Source:	Research				
Author, Year	Design	Subjects	Measurements	Results	Quality
Repka & Ray, 1993 <sup>46</sup>	Retrospective cohort	166 children with amblyopia treated for 3 months with either optical (87 subjects, average age 6.2 years) or pharmocological penalization (88 subjects, average age 5.3 years)	Improvement in visual acuity	Of those treated with optical penalization, 77% improved by the end of treatment; of those treated with pharmocologic penalization, 76% improved by the end of treatment	Fair
Woodruff et al., 1994 <sup>44</sup>	Retrospective cohort	961 subjects with amblyopia treated in England	Visual acuity	48% of the subjects had at least 20/30 vision at the end of treatment	Fair
Eustis & Chamberlin, 1996 <sup>38</sup>	Prospective cohort	25 patients aged 2.5- 9.5 years with amblyopia treated with opaque contact lenses	Lines of visual acuity or octaves of improvement	92% improved	Fair
Latvala et al., 1996 <sup>41</sup>	Prospective cohort	72 children with amblyopia treated and followed up, on average, 9 years later	Visual acuity	96% of the subjects had at least 20/40 vision bilaterally at follow-up; of those children referred before 4 years of age, 97% had better than 20/30 vision; of the older children, 86% had better than 20/30 vision	Fair
Newman et al., 1996 <sup>45</sup>	Retrospective cohort	91 children with amblyopia, 43 of which had strabismus, referred by a preschool vision program in England	Visual acuity	By the end of therapy, which took, on average 7.7 years, 87% of the subjects with amblyopia not associated with strabismus had at least 20/30 vision; 64.3% of those with strabismic amblyopia had at least 20/30 vision	Fair
Simons et al., 1997 <sup>49</sup>	Retrospective cohort	163 patients with strabismic amblyopia, treated with atropine (38 subjects, average age 5.4 y), intermittent atropine (73 subjects, average age 6.1 y), or optical penalization (52 subjects, 6.1 y)	Binocular vision	95% of the subjects in the atropine group, 89% of intermittent atropine group, and 77% of optical penalization group had binocular vision	Fair

**Evidence Table 4. Key Question 4: Treatment of Amblyopia** 

Source:	Research				
Author, Year	Design	Subjects	Measurements	Results	Quality
Bowman et al., 1998 <sup>40</sup>	Prospective cohort	87 subjects with amblyopia who were initially detected by, on average 4.1 years, received treatment until, on average 7.5 years, and then followed up, on average, at 12.3 years of age	Improvement in visual acuity	83% of the subjects improved by completion of therapy; 79% mainained or improved visual acuity by follow-up	Fair
Beardsell et al., 1999 <sup>42</sup>	Retrospective cohort	246 children with amblyopia (68% with strabismus, 32% with anisometropia) treated with occlusion	Visual acuity	Of those with esotropia, 85% had at least 20/30 vision, with anisometropia, 95% had at least 20/30 vision	Fair
Krumholtz & FitzGerald, 1999 <sup>39</sup>	Prospective cohort	52 children younger than 14 yr old with refractive amblyopia treated with either optical correction(17 subjects), optical correction and patching(23 subjects), or vision therapy (12 subjects) and followed for 6 months	Improvement in visual acuity	Overall, optical treatment resulted in 41% improvement; optical treatment and patching led to 69% improvement; vision therapy led to 67% improvement; of those children 2 yrs to 5yrs 11 months, 45% (5 out of 11 subjects) had improvement	Fair

**Evidence Table 5. Key Question 5: Treatment of Non-amblyopiagenic Visual Impairment** 

Source: Author,	, Research				
Year	Design	Subjects	Measurements	Results	Quality
Newman et al., 1996 <sup>45</sup>	Retrospective cohort	100 children in England with refractive error but without amblyopia or strabismus	Visual acuity	98% of the children improved to at least 20/20 in the corrected eye. 2% achieved 20/30 in the corrected eye	Fair

**Evidence Table 6. Key Question 6: Health Outcomes** 

Source: Author, Year	Research Design	Subjects	Measurements	Results	Quality
Tommila & Tarkkanen, 1981 <sup>53</sup>	Identification of cases and comparison to total population	23 subjects from Finland with amblyopia who had lost vision in the sound eye during the previous 20 years	Rate of vision loss	Risk of vision loss in healthy eye is 1.75+- .30/1000 compared to an estimated 0.66/1000 in the general population	Poor
Stewart-Brown et al., 1985 <sup>51</sup>	Cross-sectional	12,905 10 year old children in England	British Ability Scales. This test has a mean score of 100 points and standard devation of 15 points	<u> </u>	Good
Packwood et al., 1999 <sup>52</sup>	Cross-sectional survey	45 adults with amblyopia, but without strabismus, were recruited from a university-based ophthalmology clinic; there were 25 respondents	New and previously unvalidated survey	The respondents reported that amblyopia interferes with school (52%) and work (48%); furthermore, amblyopia affects lifestyle (50%), ability to participate in sports(40%), and influences job choice (36%); the respondents reported worrying about losing better eye (24%); 76% reported that amblyopia affects their self image (76%)	Poor

<sup>\*</sup>N/A = Not applicable.

**Evidence Table 7. Key Question 8: Adverse Effects of Treatment** 

Source:	Research				
Author, Year	Design	Subjects	Measurements	Results	Quality
Epelbaum et al., 1993 <sup>48</sup>	Retrospective cohort	407 children in France with strabismic amblyopia beginning teatment on average at 57 months	Visual acuity in occluded eye	Mean magnitude of decrease of occluded eye during treatment was 20/182. Decrease was not permanent and almost always resolved in a few weeks	Fair
Ingram et al., 1991 <sup>54</sup>	RCT	287 children from previous study of treatment for hyperopia at 6 months of age	•	Emmetropization did not occur in 42% of children not given spectacles, compared to 31% of those not given spectacles	Poor